K002972

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1.0 Date Prepared

DEC 15 2000

September 21, 2000

2.0 Submitter (Contact)

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3.0 Device Name

Proprietary Name: MeroGel™ Control Gel ENT Surgical Dressing

Common Name(s):

Ear, Nose and Throat Synthetic Polymer Material
Non-Woven Surgical Packing
Non-Woven Wound Dressing

Classification Name: Ear, Nose and Throat Synthetic Polymer Material

4.0 Device Classification

Ear, nose, and throat synthetic polymer material — Product Code KHJ
Class II; 21 CFR 874.3620

and/or

Non-Woven Wound Dressing, Unclassified,
Potentially applicable product codes: KMF, MGQ and MGP

5.0 Device Description

MeroGel™ Control Gel ENT Surgical Dressing is a biomaterial composed of HYAFF®, an ester of hyaluronic acid, a natural occurring constituent of the extracellular matrix. The material may be compressed and shaped by the surgeon according to the individual patient's needs for use as a space-occupying implant material. MeroGel™ Control Gel ENT Surgical Dressing comes in various size and quantity configurations for the convenience of the surgeon, depending on the quantity needed for the specific procedure being performed. Due to its absorption properties, MeroGel™ Control Gel ENT Surgical Dressing may be used to help control minimal bleeding. In contact with body fluids, it rapidly changes into viscous and transparent gel, conforming to tissue surfaces and eventually dissolves.

6.0 Intended Use

MeroGel™ Control Gel ENT Surgical Dressing is a dressing and/or stent intended to separate tissue or structures compromised by surgical trauma, help control minimal bleeding, and act as an adjunct to aid in the natural healing process. The device is indicated for use in ear, nose, and throat, head and neck surgical procedures where an open wound dressing and/or stenting material is required including the middle ear and external ear canal following myringoplasty, tympanoplasty, canalplasty, stapes and mastoid surgery, also for use in the nasal and/or sinus cavities following nasal, sinus, and/or throat surgery where separation of tissues or structures is desired.

7.0 Substantial Equivalence

MeroGel™ Control Gel ENT Surgical Dressing™ is substantially equivalent to Medtronic Xomed's currently marketed devices MeroGel™ Nasal Dressing and Sinus Stent and MeroGel™ Otologic Pack. MeroGel™ Control Gel ENT Surgical Dressing™ is also substantially equivalent to ConvaTec's Hyalofill® HA Absorbent Wound Dressing in technological characteristics and intended use. The combined intended uses of these predicate devices are as an open wound dressing for a variety of surgical procedures of the ear, nose, throat, head, and neck.

MeroGel™ Control Gel ENT Surgical Dressing™ is made from the same base material as all three predicate devices listed above. Both the predicate devices and the subject device are benzyl esters of hyaluronic acid made by the identical manufacturing processes. The subject and predicate devices are sterile single use devices made from materials which have demonstrated satisfactory biocompatibility.

In conclusion MeroGel™ Control Gel ENT Surgical Dressing raises no new issue of safety or effectiveness.

TABLE 1 **Substantial Equivalence Table**

Intended Use	open wound dressing and/or stent intended to separate tissue or structures comprised by surgical trauma, help control minimal bleeding, and act as an adjunct to aid in the natural healing process	space-occupying dressing or stent to separate mucosal surfaces and to help control minimal bleeding following surgery	space occupying dressing and/or stent intended to separate mucosal surfaces, help control minimal bleeding and act as an adjunct to aid in the natural healing process.	Management of deep exuding wounds, sinuses and fistulae
Indications	ENT, head, and neck surgical procedures where a dressing and/or stenting material is required including the middle ear and external ear canal following myringoplasty, tympanoplasty, canalplasty, stapes and mastoid surgery, also for use in the nasal and/or sinus cavities following nasal, sinus, and/or throat surgery where separation of tissues or structures is desired.	nasal/sinus surgery	middle ear and external ear canal following canalplasty, myringoplasty, tympanoplasty, stapes and mastoid surgery	External wounds both surgical and non-surgical
Base Material	biocompatible polymer, esterified hyaluronic acid (HYAFF® 11)	biocompatible polymer, esterified hyaluronic acid (HYAFF® 11)	biocompatible polymer, esterified hyaluronic acid (HYAFF® 11)	biocompatible polymer, esterified hyaluronic acid (HYAFF® 11)
Percent Esterification	60.0 – 68.5%	73 – 82%	73 – 82%	60.0 – 68.5%
Absorbent Qualities	in excess of 6 times weight of the device	in excess of 10 times weight of the device	in excess of 10 times weight of the device	in excess of 6 times weight of the device
Sterility	yes - gamma irradiation	yes - gamma irradiation	yes - gamma irradiation	yes - gamma irradiation
Biocompatibility	yes - ISO 10993 1-12	yes - ISO 10993 1-12	yes - ISO 10993 1-12	yes - ISO 10993 1-12
Method of Action	hygroscopic, forms gelatinous mass in contact with fluids	hygroscopic, forms gelatinous mass in contact with fluids	hygroscopic, forms gelatinous mass in contact with fluids	hygroscopic, forms gelatinous mass in contact with fluids
Method of Removal	none required (gentle irrigation can be used, as necessary)	none required (gentle irrigation can be used, as necessary)	none required (gentle irrigation can be used, as necessary)	none required (gentle irrigation can be used, as necessary)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2000

Ms. Diana Preston Taylor
Sr. Regulatory Affairs Specialist
Medtronic Xomed
6743 Southpoint Dr. N.
Jacksonville, FL 32216-0980

Re: K002972
Trade Name: MeroGel™ Control Gel ENT Surgical Dressing
Regulatory Class: II
Product Code: KHJ
Dated: September 21, 2000
Received: September 22, 2000

Dear Ms Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Intended Use Statement

510(k) Number (if known): K002972

Device Name: MeroGel™ CONTROL GEL ENT Surgical Dressing

Indications for Use:

MeroGel™ Control Gel ENT Surgical Dressing is a dressing and/or stent intended to separate tissue or structures compromised by surgical trauma, help control minimal bleeding, and act as an adjunct to aid in the natural healing process. The device is indicated for use in ear, nose, and throat, head and neck surgical procedures where an open wound dressing and/or stenting material is required including the middle ear and external ear canal following myringoplasty, tympanoplasty, canalplasty, stapes and mastoid surgery, also for use in the nasal and/or sinus cavities following nasal, sinus, and/or throat surgery where separation of tissues or structures is desired.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002972

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